Eur J Vasc Endovasc Surg (2011) 41, 337–343

Outcome and Safety of Aorfix™ Stent Graft in Highly Angulated Necks – A Prospective Observational Study (Arbiter 2)

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Submitted 14 April 2010; accepted 7 November 2010
Available online 8 December 2010

KEYWORDS
Abdominal aortic aneurysm;
Neck;
Endovacular repair;
Stent graft

Abstract *Objectives:* Severe neck angulation is associated with poor outcome following endovascular aneurysm repair. The aim was to study the safety and early outcome of patients with infrarenal aortic aneurysms with severe neck angulation (60–90°) treated with the Aorfix™ endovascular stent graft.
Design/methods: This was a non-randomized prospective observational study of 30 patients with infra-renal abdominal aortic aneurysms with highly angulated necks. Outcomes were primary technical success, 30 day and short term (30 days–6 months) clinical success and other patient morbidity at 30 days.
Results: Median neck angulation was 81.2°. Initial technical success was 93.3% ($n = 28$) with 2 stents deployed too low. Intra-operatively 3 patients initially had type I endoleaks, but all were resolved by ballooning. 30 day clinical success was 96.7%: there were no type I or type III endoleaks observed, and no reports of graft thrombosis or migration. Early clinical failure was accounted for by one perioperative death (3% mortality). No aneurysm-related interventions were required during follow-up. At 6 months two patients were reported as having type I endoleaks, although both sacs have reduced in size. Neither has required intervention. No patient has died due to aneurysm rupture or required removal of the endograft.
Conclusion: The results of this study support the continued application of the Aorfix™ graft to the highly angulated neck.

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1078-5884/$36
doi:10.1016/j.ejvs.2010.11.008

Introduction

Endovascular repair (EVAR) is now increasingly applied[1] and accepted as a treatment for infra-renal abdominal aortic aneurysms.[2,3] The suitability of a patient for EVAR is dependent on the patient's aorto-iliac anatomy adhering to the manufacturer's instructions for use (IFU). Typically manufacturers recommend a neck length of minimum 15 mm (10 mm for Endurant™ Stent Graft System (Medtronic, Inc, Santa Rosa, California)), $<60^\circ$ infrarenal neck angulation ($<75^\circ$ infrarenal angulation where neck length is >15 mm for the Endurant™), and a proximal neck diameter of up to 32 mm with 10—20% oversizing of the graft. Non-adherence to the IFU is strongly associated with poorer outcomes, particularly type I endoleaks.[4,5] Despite this, over a ten-year period, over 20% ($n = 1152$) of patients recorded in the EUROSTAR EVAR registry had aneurysms with severe neck angulation ($>60^\circ$). There were significant increases in proximal endoleaks, graft migration and neck dilatation in this subgroup.[6]

The Aorfix™ aortic stent graft is a modular device composed of a circular Nitinol frame covered by a woven polyester fabric. This structure, in contrast to the rigid z-stent design of other commercially available stent grafts, is extremely flexible and readily compliant with tortuous vessels (Fig. 1). A previous prospective multicentre study has demonstrated the utility of the Aorfix™ stent in patients with infrarenal neck angulation of up to 65°.[7] Furthermore bench testing has shown that unlike other grafts, neck angulation has no influence on type I endoleak rate with the Aorfix™ device.[8]

The aim of this prospective multicentre trial was therefore to study the safety and early outcome of patients with infrarenal aortic aneurysms with severe neck angulation (60—90°) treated with the Aorfix™ stent graft.

Methods

Study design

This was a prospective non-randomized observational study conducted across 9 European centres. Recruitment and treatment of patients occurred between June 2006 and September 2008. The device and technique has been described in detail previously.[7]

Patients were considered eligible for the trial if they had an abdominal aortic aneurysm of >50 mm diameter, with an infrarenal neck length >15 mm and angulation of between 60° and 90° as assessed by CT scan in 3 dimensions. Patients also required aorto-iliac anatomy for endovascular aneurysm repair in keeping with the previously published IFU for the Aorfix™ device[7] (i.e. a non-aneurysmal neck length of >15 mm below the renal arteries and >20 mm below the superior mesenteric artery; common iliac artery diameter must be greater than 7 mm (inner wall to inner wall)), with an appropriate distal landing length (minimum 9 mm). Patients with connective tissue diseases and renal failure (creatinine >176 μmol) were not eligible for the study. Patients outside the anatomical criteria (e.g., angulation $>90^\circ$) could be treated with the graft as part of the study with local consent.

The study protocol required all patients to be assessed at 72 h or discharge, 30 days and 6 months post procedure. Assessment at 30 days was either with duplex ultrasound or CT dependent on the preference of the clinician. All patients underwent CT angiography at 6 months.

Outcomes

The outcomes assessed were technical success, early clinical success, early morbidity, short term clinical success and stent migration rate. We have reported outcomes on the basis of intention to treat.

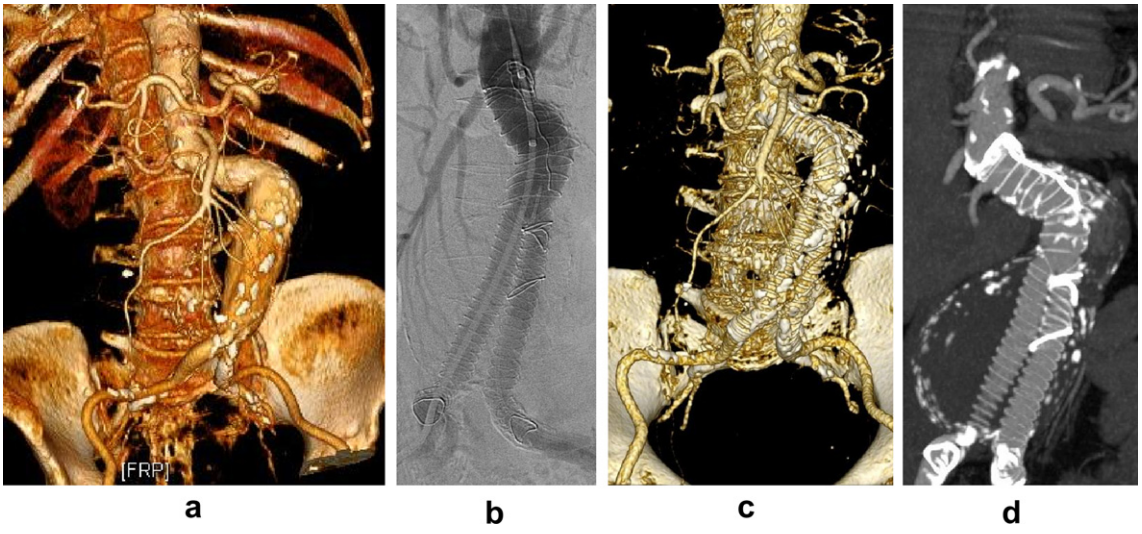

Figure 1 Aorfix stent graft in a patient with highly angulated anatomy; pre-operative CT (a) shows an infra-renal abdominal aortic aneurysm with neck angulation of just under 90°; intra-operative DSA (b) demonstrates the positioning of the graft and post-operative CT (c) and (d) demonstrate the conformity of the graft to the patient's anatomy.

Reporting standards[9] state that technical success (peri-procedural events occurring from the start of the procedure and extending through the first 24 h) involves the following components: successful access to the arterial system using a remote site; successful deployment of the endograft with secure proximal and distal fixation with the absence of type I or III endoleak and a patent graft without significant twist, kink or obstruction. Technical success includes the use of adjuncts including modular components, stents, angioplasty or surgical procedures. If these adjuncts are unplanned then the term assisted primary technical success is applied. Clinical success is defined as "successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, type I or III endoleak, graft infection or thrombosis, aneurysm expansion (diameter <5 mm, or volume <5%), aneurysm rupture, or conversion to open repair". Clinical success was measured at 30 days (early) and between 30 days and 6 months (short term).

Beyond the planned duration of the study, data has been collected on an annual basis and 12 month follow-up outcomes are also reported in this study.

Results

Patient demographics and aneurysm morphology

30 patients were recruited and underwent treatment. Demographics and aneurysm morphology are summarized in Tables 1 and 2.

Procedural information

Epidural anesthesia was used in the majority of cases ($n = 23$). The mean duration of operation was 134 min (range: 35–271 min), with a mean screening time of 34 min (range 10–81 min). Mean blood loss was 335 ml (range: 80–1700 ml), with four subjects requiring a blood transfusion. Fifteen patients were managed post-operatively on intensive care for at least 1 day (range 1–3). Mean inpatient length of stay was 4.5 days.

Table 1 Patient demographics.

Demographics	
Male sex	23
Mean age	77.4 yrs (Range 59–95)
Co-morbidity	**n**
Smoking	
Current	6
Ex	18
Previous MI	10
Hypertension	11
Chronic obstructive pulmonary disease	5
Renal impairment	8
Anti-platelet use	19
ASA grade	
ASA II	13
ASA III	16
ASA IV	1

Table 2 Anatomical features.

Aneurysm morphology	Mean (range)
Mean Size	69.3 mm (55–109 mm)
Infra-renal angulation	81.2° (63–110°)
Neck length	26.2 mm (11–40 mm)
Neck diameter	24.4 mm (19.2–29.2 mm)
Other features	**n**
Adverse neck shape	
Conical	4
Barrel	6
Neck calcification	
Moderate	14
Severe	5
Excessive neck thrombus	0
Iliac tortuosity	
Moderate	11
Severe	10

Protocol violations

7 patients were treated outside the eligibility criteria of the trial, 2 with elevated serum creatinine >176 μmol, 4 with a neck angle of greater than 90° (92°, 96°, 99°, 110°) and 1 with neck length less than 15 mm (11 mm). The principal investigator in each centre made the clinical decision to enter the patient into the study.

Follow-up

Per-protocol 30 day follow-up data was available for 29 patients and six month data was available for 27 of the 30 patients (patient deaths $n = 3$). 12 month CT has been performed in 21. Three further patients are alive, but have not been imaged and the three remaining patients are lost to follow-up.

Outcomes

Technical success

There were two primary technical failures, where the device was positioned too low to gain secure proximal fixation and an unplanned proximal extender was used. Three patients had a type I endoleak following deployment; however all were obliterated on completion angiography by ballooning. As ballooning is a planned adjunct for the deployment of the Aorfix™ stent graft these cases should not be considered to be primary technical failures.[9] Primary technical success was 28/30 (93.3%) and assisted primary technical success was 30/30 (100%). No patient required conversion to an open aneurysm repair.

Three patients had the endograft inaccurately deployed resulting in partial or complete coverage of a visceral aortic branch. In one patient a renal artery was partially covered

without change in measured renal function. Two patients had inaccurate placement of an iliac limb resulting in inadvertent coverage of an internal iliac artery. One of these patients suffered mild buttock claudication. Despite deployment too high or too low (adverse events) these patients satisfy the definition of technical success as the aneurysm was excluded with a patent graft, and without type I or III endoleak.[9]

30 day clinical success

There was one death within 30 days. This patient developed a critically ischaemic leg post procedure due to a right superficial femoral artery occlusion requiring angioplasty and stenting. Following this (day 2 post-operatively) he developed abdominal pain, hypotension and a lactic acidosis; at laparotomy he was found to have infarcted intestine due to occlusion of the superior mesenteric artery (SMA). The patient did not undergo post mortem examination and it is unknown whether the stent graft was occluding the origin of the artery.

There were no type I or type III endoleaks at 30 days. 6 patients had aneurysm sacs which were measured as larger than on the pre-procedural scan; with a mean expansion of 2 mm (range 1—4 mm), although no patient had aneurysm expansion of >5 mm or 5% volume. There were no reports of graft thrombosis, infection, migration, aneurysm rupture or conversion to open repair. 30 day clinical success was 29/30 (1 death) — 96.7%.

30 day morbidity

Five patients had local-vascular complications (16.6%). One patient had significant haemorrhage from the femoral artery during the procedure. Two patients had limb threatening ischaemia in the early post operative period; one of whom has already been described. The second patient had thrombotic occlusion of the common femoral artery and required thrombectomy and common femoral endarterctomy 2 days post procedure. One patient had distal embolisation to the fifth toe. This required amputation of the affected digit. Finally one patient with a covered internal iliac artery had mild buttock claudication as described.

There were four subjects who had minor post operative wound problems (seromas $n = 3$ and wound infection $n = 1$; 13.3%).

Two patients' serum creatinine levels became abnormally raised post procedure (138 μmol/l and 147 μmol/l). No patient required renal support within 30 days. Both patients' creatinine remained elevated at 6 months (138 μmol/l and 157 respectively μmol/l). The cause of renal impairment is unknown. One patient developed a bradycardia on day one post operation; this required temporary placement of a pacing wire for 48 h. One patient developed a post-operative chest infection (day 7).

Short term clinical success (30 days—6 months)

There were two further deaths, although neither aneurysm-related. The first patient required a permanent pacemaker 1 month post procedure, and despite a normal creatinine at the time of procedure was dialysis dependent 3 months post operation (aetiology unknown). The subject developed angina and left ventricular failure and suffered a fatal cardiac arrest 121 days post procedure. The second patient developed acute renal failure due to *Clostridium difficile* infection, and died 168 days post procedure due to a chest infection.

Two type I endoleaks were observed at 6 months — both of these are recurrent. Neither patient has sac expansion; — as such the local investigators have adopted a conservative approach in both patients. There were no reported type III endoleaks, graft thrombosis, infection, migration, aneurysm rupture or conversion to open repair. Clinical success between 30 days and 6 months was therefore 25/27 — 92.6% (failure in 2 patients with type I endoleak).

Six patients had expansion of the aneurysm sac from baseline scanning, with a mean increase of 3 mm. Four patients had no change in sac size, whilst 15 had a reduction in sac diameter (mean 6.7 mm).

12 month clinical success

All 24 of the patients with follow-up data to one year are alive, with no aneurysm rupture, graft thrombosis or infection. Of the 21 patients who have undergone imaging there were no reports of graft migration. There have been no interventions in this time period. Mean aneurysm sac size has decreased by 6.1—63.2 mm (14 patients- decrease in sac size; 6 patients no change and 1 patient- increase 2 mm).

One patient has a persistent type I endoleak at 12 months but has had no change in sac diameter. The second subject who was reported as having a type I endoleak at 6 months, was reported at 12 months as having a type II rather than a type I endoleak. The aneurysm sac in this patient had decreased from 66 mm to 64 mm.

Discussion

This study has demonstrated that the Aorfix™ device can be used to treat patients with aneurysms with highly angulated infra-renal necks with high short term technical and clinical success.

In this study of 30 patients all had neck angle of >60° and nineteen (63%) had a neck angle of >75°. The level of primary technical success in this study (93.3%) is comparable with the performance of other contemporary commercial devices applied to far less angulated neck anatomy — for example the Medtronic Endurant™ graft system had a success rate of 90.3%[10] in a study of patients with neck angulation of up to 75°. However, only six patients (15%) in this study had neck angulations of >60°. In a further study of the Endurant[11] graft the authors report a "30 day technical success rate of 44/45 (97.8%) and clinical success rate of 43/45 (95.6%)". In this study 26(58%) patients in the cohort had a neck angle of >60°. However the authors have used different definitions of success to that which is recommended.[9] Five patients required unplanned intra-operative adjuncts (iliac stenting); as such primary technical success was only 88.8%.

In the EVAR 1 trial in the endovascular treatment arm ($n = 512$) the level of technical and/or clinical success is not defined. However the use of unplanned adjuncts (extenders $n = 114$, cuffs $n = 16$, non-covered stents $n = 18$) was extremely high ($n = 148$; 28.6%); thus primary technical success was just over 70%.[2] Furthermore in the first 30 days 8 patients died, 10 required conversion to open repair, and 18 patients required a secondary intervention for endoleak. Thus the level of clinical failure was at least 37/512 (7.0%).[12] We report early clinical success rate of 96.7% in a group of patients with what had previously considered highly unfavorable anatomy. Indeed over a third of patients had severe iliac angulation as well as severe neck angulation, which is recognized as an issue in EVAR.[13]

The technical failures in our study occurred due to low deployment — both successfully managed by a proximal extension. This problem was also noted by Albertini[7] in a similar sized series of patients with less severe angulation, where four patients (14.0%) had the graft deployed too low. There was also inaccurate deployment in three other patients — these are adverse events and not technical or clinical failures. Two patients, both of whom had neck angulations of $>90^{\circ}$, had unplanned coverage of internal iliacs. The third had partial coverage of a renal artery without clinical consequence. The top end of the Aorfix™ graft has a "fish mouth" and requires accurate orientation of the graft. Ideally the graft should be deployed with the troughs embracing the renal ostia and the anterior peak of the fish mouth positioned below the origin of the superior mesenteric origin. Highly angulated anatomy creates foreshortening and often requires angulation of source and detector during deployment and angiography,[14] whilst iliac angulation may make it difficult to rotate the stent graft, as required for orientation of the fish mouths. It is undisputable that there is a learning curve for treating such complex anatomy, in addition to using the Aorfix graft™. The clinical and technical failures in this study should be considered in this context.

One patient died in this study, giving a 30 day mortality of 3.3%. Although this mortality rate is higher than large prospective randomized studies comparing open and endovascular aneurysm repair,[2,3,15] the average age of the patients in this study was over five years older. The mortality rate is in keeping with contemporary single centre series which range from 0[16]—8%[17] .In particular the mortality rate is lower than the 4.0% mortality reported for patients with severe neck angulation in the Eurostar registry.[6] It is undisputed that the death in the study patient was related to the treatment of the aneurysm, however it is not possible to ascertain the exact role the stent played as the patient did not undergo a post mortem examination.

At six month the aneurysm-related and all cause mortality rate in this series was 3.3% and 10% respectively. It is likely the deaths outside the perioperative period reflect the co-morbidity of this elderly cohort, although only two patients in this series had been formally turned down for open repair.

The level of morbidity following EVAR is often unreported — for example 30 day morbidity is not reported in EVAR 1.[12] Four patients in this study had wound related problems (seroma, haematoma or infection). We acknowledge that these minor complications are reported at a higher rate than in other trials (e.g., DREAM 3.5%). In the DREAM[3] trial 16.4% of patients had a local-vascular or implant related complication. This is similar to the rate described in our study: two patients had limb threatening ischaemia (including the subject who died), one had distal embolisation, one had significant groin haemorrhage per-procedure and one had claudication due to coverage of the internal iliac (5/30 — 16.6%). Overall, at thirty days the level of secondary intervention was 10% (two operations for limb ischaemia likely related to underlying femoral disease and one minor amputation). It is worthy of note that vascular complications are probably far more frequent than previously thought — a recent study of 134 patients found that 25% had a significant common femoral or external iliac dissection on duplex following endograft placement.[18] The authors state that dissection was unrelated to device type; as such the local complications in this study should not simply be attributed to the device used in this series.

The Eurostar data[6] has shown that use of the Talent™ (Medtronic), Zenith™ (Cook) and Excluder™ (Gore) stent grafts in patients with severe neck angulation is associated with greater than two fold increase in both early (30 day) type I endoleak and stent migration. At 30 days, 4.9% of the 1152 patients with severe neck angulation had a type I endoleak and 1.6% of stent grafts had migrated. A recent single centre, device specific performance study in high angled neck aneurysms, found that the Zenith™ (Cook) and the Talent™ (Medtronic) grafts had a 19% and 53% proximal type I endoleak rate respectively (median 16 month follow-up).[19] It is suggested that suprarenal fixation may reduce adverse events associated with hostile neck anatomy; however graft kinking and infolding may be a problem with angulation of $>60^{\circ}$.[20] The concentric nitinol ring structure of the Aorfix™ stent graft provides conformability in severe angulation without kinking. Despite a lack of supra-renal fixation, prospective studies in patients with high neck angulation have shown no evidence of Aorfix™ graft migration.[7]

In this study at 30 days, no patient had a type I endoleak detected and there was no evidence of any graft migration. These results are promising; they clearly improve upon the Eurostar data, which is only directly comparable at 30 days (4.9%). However at 6 months, 2 patients were reported as having developed a proximal type I endoleak. Neither have any evidence of graft migration or sac expansion; indeed the sacs have reduced in size by 1 mm and 3 mm respectively. It is worth re-iterating that the diagnosis of all endoleaks and treatment decisions were made by individual practitioners. Both patients with type I endoleaks at 6 months had required intra-operative ballooning prior to completion angiography to abolish apparent type I endoleaks. The first subject, an 83-year-old female had a neck angle of 90°, with a 20 mm neck which was barrel shaped and 22 mm in diameter above an aneurysm of 67 mm. The presence of a non-parallel neck increases the risk of proximal endoleak.[21] However at 12 months, this patient was reported as having a type II and not a type I endoleak. Furthermore the sac size has decreased further, suggesting this is a benign endoleak. The second subject, a 77-year-old male had a neck diameter of 29 mm, neck length of only 11 mm, neck angle of 71° and an aneurysm of 61 mm. The

short aneurysm neck is outside the eligibility criteria of the study but a decision to proceed was made locally. Short neck length is a risk factor for late type I endoleaks[5,21] and in this patient the endoleak persisted at 12 months with no change in sac size. The Eurostar data suggests that the relative risk of late proximal endoleak in patients with neck 10–14 mm (9.6%) is twice that of patients with a length of >15 mm (3.4%). However this was not associated with increased risk of re-intervention, sac expansion or aneurysm-related death. Both patients will be followed closely and longer term results regarding re-intervention in this study group are keenly anticipated. Importantly in this study, once beyond the first 30 days, no subject has undergone any form of re-intervention.

We fully acknowledge that this is a small study, which has limitations. It is a highly selected population with a high-number of local violations to inclusion criteria, particularly relating to neck angulation. The inclusion of such patients in the trial was a matter of local consent; however it is important to emphasise that these patients did not have anatomy which conformed to the IFUs of other currently available. In terms of selection bias; the study did not collect information on patients with suitable anatomy who were excluded from the trial. Despite this potential bias, the study remains a transparent assessment of the graft in patients with highly angulated anatomy. The number of patients in the study is small – with only 25 adhering to the anatomical inclusion parameters. Whilst some may argue that apparent high clinical success in such a sized group is a type II error – it is also true that any morbidity and mortality is potentially magnified. However, such numbers are usual for this type of early safety and efficacy study. For example the initial Talent graft study reported 30 day outcomes for just 25 patients.[22] It is worthwhile noting that in this study group the initial technical success was just 78% and the 30 day mortality was 12% (3 patients).

We contend that despite the methodological limitations of this study, the results support the continued application of the Aorfix™ stent graft to the highly angulated neck. Data from this study and the Retrospective Aorfix™ Data Retrieval (RADAR) registry has confirmed graft safety and good clinical outcomes allowing a CE marking and IFU allowing the treatment aneurysms with up to 90° neck angulation. Long term follow-up and larger studies are required to evaluate the durability of the early results.

Ethical Approval

Ethical approval was obtained in each of the five European countries (United Kingdom, Germany, Netherlands, Poland and Spain). Written informed consent was obtained from all participants.

Funding

The study was funded by Lombard Medical.

Conflicts of Interest

Dr John Hardman has been paid fees for consulting and speaking by William Cook Europe and by Lombard Medical.

Appendix

The authors report this trial on behalf of the Arbiter 2 trial participants (trial representative listed from each unit). The number of patients recruited and treated per centre is shown in parenthesis.

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